510(K) Summary, 510(k) K122550

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Date Prepared: January 13, 2012

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1. **Identification of the Device:**
   Proprietary-Trade Name: **ICS Impulse**
   Classification Name: Class II, Product Codes: GWN and LXV, Device: Nystagmograph
   Common/Usual Name: Vestibular testing device

2. **Equivalent legally marketed devices**: Micromedical Technologies Inc. Vorteq, K891008 and Micromedical Technologies Inc. VisualEyes K964325.

3. **Description of the Device**: The device is a combination of hardware and software. The patient wears a pair of lightweight, tightly-fitting goggles on which is mounted a very small, very light, very fast, fire-wire video camera and a half silvered mirror. This transparent mirror reflects the image of the patient's eye into the camera. The eye is illuminated by a low-level infra-red light emitting diode which is not visible to the patients. A small sensor on the goggles measures the head movement. The whole goggle system is lightweight but it must be secured tightly to the head to minimize goggle slippage. The software records and displays the information obtained during what is known as a "head impulse test" The basic head impulse test starts with the tester standing behind the patient who is wearing the goggles. While the patient is asked to stare at the fixation dot placed on a projection surface in front of them, the tester rotates the patient's head horizontally through a small angle (about 10-20 degrees) in a brief, abrupt and unpredictable manner, varying the direction and the velocity. The goggles collect both head and eye data. The gyroscope measures the velocity of the head movement (the stimulus). The high-speed camera captures the image of the eye. The OTOsuite Vestibular software processes the head velocity data and velocity data for eye movement (the response). Simultaneous displays of the data for head movement and for eye movement allow the clinician to determine if the response is within normal limits or not.

4. **Indications for Use (intended use):** The ICS Impulse System is used in the assessment of the vestibular-ocular reflex (VOR) by measuring, recording, displaying, and analyzing eye and head movements. (Prescription use).

5. **Safety and Effectiveness, comparison to predicate device**. This device has the same indications for use as the predicate device but employs different technology to accomplish the same tasks.

6. **Description of Testing:** The device passed UL Electrical Safety testing and EMC testing. Software validation and risk analysis was performed. Clinical testing compared test results to Scleral Search Coils test results. ICS Impulse adequately meets the design requirements and acceptance criteria.

7. Substantial Equivalence Chart

Characteristic	Micromedical Technologies Inc. Vorteq, K891008 and VisualEyes K964325.	ICS Impulse
Intended Use:	VORTEQ® is designed to provide information about the Vestibular Ocular Reflex (VOR) in patients with dizziness or balance problems.	The ICS Impulse System is used in the assessment of the vestibular-ocular reflex (VOR) by measuring, recording, displaying, and analyzing eye and head movements.
Configuration	VORTEQ® utilizes an angular velocity sensor mounted directly to the VisualEyes™ FireWire Binocular Goggles. With the VisualEyes™ Monocular Goggles, the angular velocity sensor is attached to the back of the goggles headband for VORTEQ® testing	The patient wears a pair of lightweight, tightly-fitting goggles on which is mounted a very small, very light, very fast, fire-wire video camera and a half silvered mirror. This transparent mirror reflects the image of the patient's eye into the camera. The eye is illuminated by a low-level infra-red light emitting diode which is not visible to the patients. A small sensor on the goggles measures the head movement. The whole goggle system is lightweight (only about 60g) but it must be secured tightly to the head to minimize goggle slippage
Photo		
Interfaces	Firewire for Camera Data: Not specified	Firewire for Camera USB 2 for Data
Electrical safety	Electrical Safety per UL2601 - IEC-60601.	Complies with UL 60601-1, IEC 62471, 1st.ed., IEC 60825-1, 2.ed. UL Listed
EMC	Not specified	IEC 60601-1-2: 2007
Calibration	Performed using a Digital Lightbar, LCD projector or Secondary monitor. Stimulus +/- 15 degrees for horizontal and +/- 10 degrees for vertical.	Performed using 2 Built-In Laser (2) Class II @ +/-7.5 degrees.

8. **Conclusion:** After analyzing bench testing, safety, EMC, software, and clinical validation testing we conclude that the ICS Impulse is as safe and effective as the predicate device, and has essentially the same indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 1, 2013

GN Otometrics A/S
% Mr. Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Court
Naples, FL 34114

Re: K122550
Trade/Device Name: ICS Impulse
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: II
Product Code: GWN, LXV
Dated: January 21, 2013
Received: January 23, 2013

Dear Mr. Daniel Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K122550**

Device Name: **ICS Impulse**

Indications For Use:

The ICS Impulse System is used in the assessment of the vestibular-ocular reflex (VOR) by measuring, recording, displaying, and analyzing eye and head movements.

Prescription Use **X** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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